IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

PENNY HAVANICK,

Plaintiff,

v. Civil Action No. 2:12-cv-02312

C. R. BARD, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER
(*Defendant's Motion for Summary Judgment*)

Pending before the court is defendant C. R. Bard's ("Bard") Motion for Summary Judgment [ECF No. 72]. As set forth below, Bard's Motion for Summary Judgment is **GRANTED IN PART** with respect to the plaintiff's claims for manufacturing defect, breach of implied warranty, breach of express warranty, and negligent inspection, packaging, marketing, and selling. Bard's Motion for Summary Judgment is **DENIED IN PART** with respect to the plaintiff's design defect and failure to warn claims.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 58,000 cases currently pending, approximately 8,000 of

which are in the Bard MDL, MDL 2187. In an effort to efficiently and effectively manage this massive MDL, I decided to conduct pretrial discovery and motions practice on an individualized basis so that once a case is trial-ready (that is, after the court has ruled on all *Daubert* motions and summary judgment motions, among other things), it can then be promptly transferred or remanded to the appropriate district for trial. To this end, I ordered the plaintiffs and defendant to each select 50 cases, which would then become part of a "wave" of cases to be prepared for trial and, if necessary, remanded. *See* Pretrial Order ("PTO") # 102, No. 2:12-md-2187 [ECF No. 729]. This selection process was completed twice, creating two waves of 100 cases, Wave 1 and Wave 2. Ms. Havanick's case was selected as a Wave 2 case by the plaintiffs. PTO # 118, No. 2:12-md-2187 [ECF No. 841].

Ms. Havanick was surgically implanted with the Align Urethral Support System (the "Align") by Dr. Kenneth Blau at Danbury Hospital in Danbury, Connecticut. Am. Short Form Compl. ¶¶ 9–13 [ECF No. 237]. As a result of complications allegedly caused by the Align, Ms. Havanick brings the following claims against Bard: strict liability for design defect, manufacturing defect, and failure to warn; negligence; breaches of express and implied warranties; and punitive damages.[1] *Id.* at ¶ 14. In the instant Motion, Bard moves for partial summary judgment on a number of different grounds. *See* Mem. Supp. Mot. Summ. J. ("Mem. in Supp.") [ECF No. 73].

[1] Bard also filed a Motion for Partial Summary Judgment on Punitive Damages Claims [ECF No. 74]. That motion is addressed in a separate order.

II. Legal Standards

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Dash v. Mayweather*, 731 F.3d 303, 311 (4th Cir. 2013); *Stone v. Liberty Mut. Ins. Co.*, 105

F.3d 188, 191 (4th Cir. 1997).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. "When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation." *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

If a plaintiff files her claim directly into the MDL in the Southern District of West Virginia, however, as Ms. Havanick did in this case, I consult the choice-of-law rules of the state in which the plaintiff was implanted with the product. *See Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan.

17, 2014) ("For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product."). Ms. Havanick received the implantation surgery for the Align in Connecticut. Thus, the choice-of-law principles of Connecticut guide this court's choice-of-law analysis.

The parties agree, as does this court, that these principles compel application of Connecticut law. Connecticut typically follows the *lex loci deliciti* doctrine, which states "that the substantive rights and obligations arising out of a tort controversy are determined by the law of the place of injury." *O'Connor v. O'Connor*, 519 A.2d 13, 15 (Conn. 1986). Connecticut courts have held that in situations where the *lex loci deliciti* doctrine would produce irrational results, courts should also consider the choice-of-law principles found in the Restatement (Second) of Conflict of Laws. *Id.* at 21–22 ("It is therefore our conclusion that we too should incorporate the guidelines of the Restatement as the governing principles for those cases in which application of the doctrine of *lex loci* would produce an arbitrary, irrational result."). Under the Restatement (Second) analysis, "[i]n an action for a personal injury, the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship." Restatement (Second) of Conflict of Laws § 146 (1971). Here, the alleged wrong occurred in Connecticut, and Connecticut has the most significant

relationship to the claims. Thus, under either analytical framework, I apply Connecticut's substantive law to the claims in this case.

C. Connecticut Product Liability Act

As an initial matter, Bard argues that Ms. Havanick's several claims should instead be treated as one single claim governed by the Connecticut Product Liability Act (the "CPLA").[2] *See* Conn. Gen. Stat. Ann. § 52-572; *see also Winslow v. Lewis-Shepard, Inc.*, 562 A.2d 517, 521 (Conn. 1989) ("The legislature clearly intended to make our products liability act an exclusive remedy for claims falling within its scope."). The plaintiff does not contest that the CPLA governs her claims. Accordingly, each of the plaintiff's theories of recovery in this case will be deemed part of a single claim under the CPLA.

III. Analysis

Bard argues that it is entitled to partial summary judgment in this case because the plaintiff's claims lack evidentiary support. The plaintiff has agreed not to pursue manufacturing defect claims. Response 1 [ECF No. 134]. Accordingly, Bard's Motion for Summary Judgment on the plaintiff's claims for manufacturing defect is **GRANTED**. Below, I apply the summary judgment standard to each remaining claim.

[2] The CPLA, in relevant part, provides that a product liability claim under the section includes "all actions based on the following theories: Strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation or nondisclosure, whether negligent or innocent." Conn. Gen. Stat. Ann. § 52-572m.

A. Strict Liability

Connecticut has adopted the doctrine of strict liability for defective products set forth in section 402A of the Restatement (Second) of Torts ("Restatement"). *See Vitanza v. Upjohn Co.*, 778 A.2d 829, 835 (Conn. 2001). Section 402A provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement § 402A. "A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions." *Vitanza*, 778 A.2d at 835.

1. Design Defect

Connecticut has adopted comment k to Section 420A of the Restatement (Second) of Torts. *Vitanza*, 778 A.2d at 837. Comment k exempts certain products from strict liability because they are "unavoidably unsafe."[3] The interpretation and

[3] Comment k provides as follows:

> *Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the

treatment of this exemption varies. Connecticut courts consider comment k as a defense against strict liability to manufacturers of medical device companies. *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 784 (Conn. 2006) ("[W]e can see no principled reason to distinguish between a prescription implantable medical device like a pacemaker and a prescription drug."). "[C]omment k provides a defense against strict liability to manufacturers of 'unavoidably unsafe' products so long as the product is (1) properly manufactured and (2) proper warnings are given." *Moss v. Wyeth, Inc.*, 872 F. Supp. 2d 162, 167 (D. Conn. 2012).

Bard correctly asserts that it is the plaintiff's burden to prove by a preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered harm. Conn. Gen. Stat. Ann. § 52-572q(c). Bard, however, misconstrues the implications of this burden at the summary judgment stage. Bard summarily asserts that proper warnings were given with each Align product. However, Bard does not affirmatively show that the plaintiff will be unable to meet her burden. Rather, the plaintiff offers information that her

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> vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (1965).

implanting physician thought could be relevant in his decision to use Bard's product. Dr. Kenneth Blau Dep. 92:22–93:17 [ECF No. 134-2].

Bard presents no other argument on design defect. Thus, Bard has failed to meet its burden under the summary judgment standard of showing the absence of a genuine dispute as to any material fact. *See* Fed. R. Civ. P. 56(a); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 157 (1970), *superseded on other grounds by Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Therefore, Bard's Motion on the plaintiff's claim based on a design defect theory is **DENIED**.

2. Failure to Warn

In regards to failure to warn claims, the CPLA provides:

> (a) A product seller may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided.
>
> (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.
>
> (c) In claims based on this section, the claimant shall prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm.
>
> (d) A product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person best able to take or recommend precautions against the potential harm.

Conn. Gen. Stat. Ann. § 52-572q.

Furthermore, Connecticut, like most jurisdictions, follows the learned intermediary doctrine. *Montagnon v. Pfizer, Inc.*, 584 F. Supp. 2d 459, 462 (D. Conn. 2008) (citing *Vitanza*, 778 A.2d at 839). The learned intermediary doctrine precludes recovery under a failure to warn theory unless the injured party can "show that the warnings were inadequate as" given to the physician. *Id*; *see also Johannsen v. Zimmer, Inc.*, No. 3:00-cv-2270(DJS), 2005 WL 756509, at *8 (D. Conn. Mar. 31, 2005) ("A plaintiff must show, by a preponderance of the evidence, that adequate warnings were not provided and that if such warnings had been provided, the harm would have been avoided.").

Bard argues that the plaintiff cannot establish the necessary element of proximate cause for her failure to warn theory under the learned intermediary doctrine and the CPLA. Bard states that Dr. Blau, Ms. Havanick's implanting physician, testified in his deposition that even if Bard had provided all of the information that the plaintiff contends that Dr. Blau should have received, he still would have implanted Ms. Havanick with the Align. The plaintiff, conversely, contends that Dr. Blau testified multiple times in the same deposition that had he known such information, his decision to use the Align would have been affected. A review of this deposition, however, demonstrates that both parties mischaracterize Dr. Blau's testimony. Dr. Blau stated that if he possessed certain information the plaintiff claims that implanting physicians should have received and if that information was relevant and accurate, he may have viewed using the Align

differently. Dr. Kenneth Blau Dep. 92:22–93:17 [ECF No. 134-2]. Thus, the plaintiff has demonstrated that there is a genuine dispute over whether Dr. Blau would have implanted the plaintiff with the Align had he been as fully informed as the plaintiff has suggested.

Additionally, as seen above, there exists a genuine dispute about whether Bard's warnings were adequate. Thus, several genuine disputes of material fact exist regarding the plaintiff's claim based on a failure to warn theory. Therefore, Bard's Motion on the part of the plaintiff's claim based on a failure to warn theory is **DENIED**.

B. Negligence

Bard further moves for summary judgment regarding the plaintiff's claims for negligent inspection, marketing, labeling, packaging, and selling of the Align. According to Bard, the plaintiff's claim based on these negligence theories must fail because the plaintiff does not allege any type of breach of duty or allege how such a breach would have caused the alleged damage that is subject to the plaintiff's claim. In response, Ms. Havanick argues that Bard misconstrues the nature of the plaintiff's negligence argument, and that her allegations regarding the inspection, marketing, labeling, packaging, and selling of the Align comprise part of her general negligence claim, rather than distinct theories of recovery. The plaintiff asserts that Bard failed to adequately study or test its mesh products, including the Align, to determine their safety. The plaintiff then states that this is "merely a sample of the copious evidence" that the plaintiff can put forth to support this claim, but does not actually provide

any further evidence. Response at 12.

A review of the plaintiff's Count I in the Master Complaint, Master Compl. ¶¶ 62–67, No. 2:10-md-2187 [ECF No. 199], reveals that the plaintiff asserted three distinct negligence theories under "Count I." The bulk of the Count I allegations make claims for negligent failure to warn and negligent design defect. The plaintiff's other negligence allegations posit that Bard was "negligent . . . in designing, manufacturing, marketing, labeling, packaging, and selling" the Align. *Id.* at ¶ 64. Thus, the plaintiff's concerns that Bard is misconstruing the plaintiff's negligence claim are meritless; Bard simply chose to address the plaintiff's different theories of negligence separately. However, apart from reciting allegations that form the plaintiff's failure to warn and design defect claims, the plaintiff does not offer any support that Bard breached a legal duty that caused the plaintiff's injuries in their "inspection, marketing, labeling, packaging, or selling" of the Align. Accordingly, Bard's Motion on these points is **GRANTED.**

C. Express and Implied Warranties

"Courts have held that 'because the CPLA is silent as to the elements of a cause of action for breach of warranty,' plaintiffs may rely on the Connecticut Uniform Commercial Code, Title 42a of the Connecticut General Statutes." *Kuzmech v. Werner Ladder Co.*, No. 3:10-cv-266, 2012 WL 6093898, at *12 (D. Conn. Dec. 7, 2012) (citing *Walters v. Howmedica Osteonics Corp.*, 676 F.Supp.2d 44, 55 (D. Conn. 2009)). Express warranties are defined as:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain

> creates an express warranty that the goods shall conform to the affirmation or promise. (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description. (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

Conn. Gen. Stat. Ann. § 42a-2-313 (West).

Warranties "that the goods shall be merchantable is implied . . . if the seller is a merchant with respect to goods of that kind." Conn. Gen. Stat. Ann. § 42a-2-314 (West).

Bard first argues that the plaintiff's claims for breach of express and implied warranties are almost identical, and both claims state that Bard warranted that the Align was merchantable and reasonably fit. Bard then argues that these warranty claims are simply re-packaged failure to warn claims. Furthermore, in regard to a breach of express warranty, Bard argues that the plaintiff cannot prove: (1) that Bard made any express warranties to her and (2) that she relied on any information from Bard in electing to use the Align. *See Blockhead, Inc. v. Plastic Forming Co.*, 402 F. Supp. 1017, 1024 (D. Conn. 1975) ("In a breach of warranty action, a plaintiff may recover only after demonstrating that a warranty existed, that defendant breached the warranty, and that the breach was the proximate cause of the loss sustained); *see also Criteria, II Ltd. v. Co-Opportunity Precision Wood Prods., Inc.,* No. CV000803309S, 2001 WL 1178333, at *1 (Conn. Super. Ct. Aug. 30, 2001) ("reliance . . . is a necessary element of a cause of action to recover on a breach of express warranty.").

In regards to the implied warranty claim, Bard argues that there is no evidence in this case that the Align deviated from its ordinary purpose, to treat stress urinary incontinence, and, therefore, there is no breach of the implied warranty of fitness. *See Hartford Cas. Ins. Co. v. PureTech Waters of AM., LLC*, No. CV116021319S, 2012 WL 1435221, at *3 (Conn. Super. Ct. Mar. 30, 2012) ("To maintain a claim for implied warranty of fitness . . . the plaintiffs must allege a particular purpose other than [the product's] ordinary purpose.").

In response, the plaintiff alleges that the plaintiff, as well as her treating physician, were provided limited information that amount to warranties. Thus, according to the plaintiff, a genuine issue of material fact is raised as to whether the plaintiff and her physician relied on representations made by Bard.

Although the plaintiff contends Bard made warranties to her implanting physician and to her, the plaintiff does not specify what these express warranties actually were. Nor does she identify how she relied upon these alleged warranties. The plaintiff does not respond to Bard's arguments concerning her breach of implied warranty claim. Accordingly, for the reasons provided, Bard's Motion on the plaintiff's claim based on breach of warranty theories is **GRANTED.**

IV. Conclusion

For the reasons discussed above, it is **ORDERED** that Bard's Motion [ECF No. 72] is **GRANTED IN PART** with respect to the plaintiff's claim based on theories of negligent inspection, packaging, marketing, and selling, manufacturing defect, breach of implied warranty, and breach of express warranty. Bard's Motion is

DENIED IN PART with respect to the plaintiff's claim based on theories of design defect and failure to warn.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: December 6, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE